



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

11300217

**PURGED** *EK*

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

September 17, 1999

xc: HFI-35  
DWA

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 51

Patricia A. Vanacker  
Chief Executive Officer  
Eagle River Memorial Hospital  
201 Hospital Road  
Eagle River, Wisconsin 54521

Dear Ms. Vanacker:

We are writing to you because on August 25, 1999, a representative of the State of Wisconsin acting on behalf of the Food and Drug Administration (FDA) inspected your mammography facility. This inspection (ID = 1111460006) revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 and Level 2 Non-Compliances at your facility:

Level 1 Non-Compliances:

1. On six days mammograms were processed in film processor (~~~~~  
~~~~~ M35 / M35A-M) when it was out-of-limits.

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2. Phantom QC records were missing for seven weeks for mammography unit (~~~~~).
3. Processor QC records were missing for five consecutive days for film processor (~~~~~M35 / M35A-M).

Level 2 Non-Compliances:

4. Processor QC records were missing three out of 18 days (17%) of operation in May 1999).
5. Corrective action for a failing image score (before further exams) was not documented for the mammography unit (~~~~~ DMR).
6. Corrective actions for processor QC failures were not documented at least once for film processor (~~~~~M 35 / M35A-M).
7. Interpreting physician ~~~~~did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

*Note: Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. For "Continuing" requirements this includes either lack of appropriate CME/24 months or Number of Interpretations/36 months. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999.*

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for

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the cost on on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records. (Note: patient names or identification should be deleted from any submitted copies.)

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

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If you have specific questions about mammography facility requirements or about the content of this letter please feel free to contact Mr. Garvin at (414) 771-7167 x 12.

Sincerely,

A handwritten signature in black ink, appearing to read "Edwin S. Dee". The signature is fluid and cursive, with a large initial "E" and a long, sweeping underline.

Edwin S. Dee  
Acting Director  
Minneapolis District